



TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 040283-0213
INTERNATIONAL APPLICATION NO. PCT/GB2003/003168	INTERNATIONAL FILING DATE 7/24/2003	U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5) 10/522,873 PRIORITY DATE CLAIMED 8/2/2002
TITLE OF INVENTION SUBSTITUTED THIENYL-HYDROXAMIC ACIDS AS HISTONE DEACETYLASE INHIBITORS		
APPLICANT(S) FOR DO/EO/US Janet Ann ARCHER et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> has been communicated by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US) 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <input type="checkbox"/> is attached hereto. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <input type="checkbox"/> are attached hereto (required only if not transmitted by the International Bureau). <input type="checkbox"/> have been communicated by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
Items 11 to 20 below concern other document(s) or information included:		
11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98 (2 pages); PTO Form SB08 (3 pages) and copies of 39 of 42 listed references. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input type="checkbox"/> Other items or information:		

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/522,873		INTERNATIONAL APPLICATION NO. PCT/GB2003/003168		ATTORNEY'S DOCKET NUMBER 040283-0213	
The following fees have been submitted:					
21. <input checked="" type="checkbox"/> Basic national fee		\$300		\$	300.00
22. <input checked="" type="checkbox"/> Examination fee				\$	200.00
If international preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)		\$100			
All other situations		\$200			
23. <input checked="" type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority		\$100			
International Search Report prepared and provided to the Office		\$400			
All other situations		\$500		\$	500.00
TOTAL OF ABOVE 21, 22 and 23 =				\$	1000.00
<input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$ for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
214 - 100 =	114 /50 =	3	x \$250.00	\$	750.00
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e))				\$	0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total Claims	33 - 20 =	13	x \$ 50.00	\$	650.00
Independent Claims	1 - 3 =	0	x \$ 200.00	\$	0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$ 360.00	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	2400.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$	0.00
SUBTOTAL =				\$	2400.00
Processing fee of 130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
TOTAL NATIONAL FEE =				\$	2400.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). 40.00 per property				\$	
TOTAL FEES PREVIOUSLY PAID =				\$	2400.00
				Amount to be refunded:	
				charged:	
a. <input type="checkbox"/> A check in the amount of _____ to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. 19-0741 in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0741. A duplicate copy of this sheet is enclosed.					
d. <input type="checkbox"/> Fees are to be charge to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Foley & Lardner LLP					
Customer Number: 22428					
SIGNATURE <u>Michael D. Kaminski</u>					
NAME <u>Michael D. Kaminski</u>					
32,904					
REGISTRATION NUMBER					

May 6, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Janet Ann ARCHER et al.
Title: SUBSTITUTED THIENYL-HYDROXAMIC ACIDS AS
HISTONE DEACETYLASE INHIBITORS
Appl. No.: 10/522,873
Filing Date: 2/2/2005
Examiner: Unassigned
Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

An English translation of the foreign-language documents A23 and A26 is not readily available. Document A23 discloses psammaplin analogues of chlamydocin and Document A26 discloses simple anyl thienylhydroxamic acids. English abstracts are provided with foreign-language documents A7, A8, A10 and A20. The absence of English-language translations does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date May 6, 2005

By Michael D. Kaminski

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5490
Facsimile: (202) 672-5399

Michael D. Kaminski
Attorney for Applicant
Registration No. 32,904

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Substitute for form 1449B/PTO
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Date Submitted: May 6, 2005

(use as many sheets as necessary)

Complete if Known

Application Number 10/522,873
Filing Date 2/2/2005
First Named Inventor Janet Ann ARCHER
Group Art Unit Unassigned
Examiner Name Unassigned
Attorney Docket Number 040283-0213

Sheet 1 of 3

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	B1	2002-0065282	A1	Georges et al.	05/30/2002	
	B2	5,369,108		Breslow et al.	11/29/1994	
	B3	5,922,837		Meinke et al.	07/13/1999	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B4	EP	0 847 992	A1	Mitsui Chemicals, Inc.	06/17/1998		
	B5	EP	1 216 984	A1	Beacon Laboratories, Inc.	06/26/2002		
	B6	EP	1 216 986	A2	Beacon Laboratories, Inc.	06/26/2002		
	B7	JP	11-302173	A	Mitsui Chemicals, Inc.	11/02/1999		A
	B8	JP	11-335375	A	Mitsui Chemicals, Inc.	12/07/1999		A
	B9	WO	98/00127		RAPHAELI, Ada	01/08/1998		
	B10	WO	99/11659		Japan Energy Corporation	03/11/1999		A
	B11	WO	00/08048		Fujisawa Pharmaceutical Co., Ltd.	02/17/2000		
	B12	WO	00/38322	A1	Methylgene, Inc.	05/31/2001		
	B13	WO	01/70875	A2	Methylgene, Inc.	09/27/2001		
	B14	WO	02/22577	A2	Novartis-Erfindungen Verwaltungsgesellschaft M.B.H.	03/21/2002		
	B15	WO	02/26703	A1	Prolifix Limited	04/02/2002		
	B16	WO	02/30879	A2	Prolifix Limited	04/18/2002		
	B17	WO	02/46129	A2	Abbott Laboratories	06/13/2002		
	B18	WO	02/51842	A1	F. Hoffmann-LaRoche AG	07/04/2002		
	B19	WO	02/51846	A1	Lee et al.	07/04/2002		
	B20	WO	02/74298	A1	Ono Pharmaceutical Co., Ltd.	09/26/2002		A
	B21	WO	03/24448	A2	Methylgene, Inc.	03/27/2003		
	B22	WO	2004/14899	A1	Smithkline Beecham Corporation	02/19/2004		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	B23	CLOSSE et al., "Isolierung und Strukturaufklärung von Chlamydocin," Helvetica Chimica Acta, 1974, Vol. 57, No. 60-61, pp. 533-545.	none

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609 Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**

Date Submitted: May 6, 2005

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Sheet 2 of 3

Complete if Known

Application Number	10/522,873
Filing Date	2/2/2005
First Named Inventor	Janet Ann ARCHER
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	040283-0213

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	B24	DARKIN-RATTIRAY et al., "Apicidin: A novel antiprotozoal agent that inhibits parasite histone deacetylase," Proc. Natl. Acad. Sci. USA, November 1996, Vol. 93, pp. 13143-13147.	
	B25	EL-DEEN et al., "Synthesis and investigation of mass spectra of 3-[5'-(2'-substituent)-thienyl]benzo[5,6]coumarins," Phosphorus, Sulfur, and Silicon, 2003, Vol. 178, pp. 1463-1476.	
	B26	GEFFKEN, "Thiophenisostere der Salicylohydroxamsäure," Pharmazie, 1993, Vol. 48, H.6, pp. 407-410.	none
	B27	HIROTA et al., "Mass Spectrometric Determination of Amino Acid Sequence in Cyl-2, a Novel Cyclotetrapeptide from <i>Cylindrocylindrium scoparium</i> ," Biomedical Mass Spectrometry, 1974, Vol. 1, pp. 15-19.	
	B28	JUNG et al., "Amide Analogues of Trichostatin A as Inhibitors of Histone Deacetylase and Inducers of Terminal Cell Differentiation," J. Med. Chem., 1999, Vol. 42, pp. 4669-4679.	
	B29	JUNG et al., "Analogues of Trichostatin A and Trapoxin B as Histone Deacetylase Inhibitors," Bioorganic & Medicinal Chemistry Letters, 1997, Vol. 7, No. 13, pp. 1655-1658.	
	B30	KIJIMA et al., "Trapoxin, an Antitumor Cyclic Tetrapeptide, is an Irreversible Inhibitor of Mammalian Histone Deacetylase," The Journal of Biological Chemistry, October 25, 1993, Vol. 268, o. 30, pp. 22429-22435.	
	B31	KIM et al., "Oxamflatin is a novel antitumor compound that inhibits mammalian histone deacetylase," Oncogene, 1999, Vol. 18, pp. 2461-2470.	
	B32	MASSA et al., "3-(4-Aroyl-1H-pyrrol-2-yl)-N-hydroxy-2-propenamides, a New Class of Synthetic Histone Deacetylase Inhibitors," J. Med. Chem., 2001, Vol. 44, pp. 2069-2072.	
	B33	MAZUCCO et al., "Cell cycle regulation," American Association for Cancer Research, 93 rd Annual Meeting (Part V), April 6-10, 2002.	
	B34	RICHARDS et al., "Randomized, double-blind, placebo-controlled phase 2 study of the histone deacetylase inhibitor CI-994 plus gemcitabine (CI-994+G) versus placebo plus gemcitabine (P+G) in the treatment of patients with advanced pancreatic cancer (APC)," American Society of Clinical Oncology (ASCO), 2002 ASCO Annual Meeting, Abstract 644.	
	B35	SANDOR et al., "Phase I Trial of the Histone Deacetylase Inhibitor, Depsipeptide (FR901228, NSC 630176), in Patients with Refractory Neoplasms," Clinical Cancer Research, March 2002, Vol. 8, pp. 718-728.	
	B36	SCHMIDT et al., "Inhibitors of Histone Deacetylase Suppress the Growth of MCF-7 Breast Cancer Cells," Arch. Pharm. Med. Chem., 1999, Vol. 332, No. 10, pp. 353-357.	
	B37	SHUTE et al., "Analogues of the Cytostatic and Antimitogenic Agents Chlamydocin and NC-Toxin: Synthesis and Biological Activity of Chloromethyl Ketone and Diazomethyl Ketone Functionalized Cyclic Tetrapeptides," J. Med. Chem., 1987, Vol. 30, pp. 71-78.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached kinds of U.S. Patent Documents. ³ Enter office that issued the document, by the two-letter code (WIPO Standard St. 3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number 10/522,873	
Date Submitted: May 6, 2005		Filing Date 2/2/2005	
(use as many sheets as necessary)		First Named Inventor Janet Ann ARCHER	
		Group Art Unit Unassigned	
		Examiner Name Unassigned	
Sheet 3	of 3	Attorney Docket Number 040283-0213	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T [§]
	B38	SU et al., "A Novel Istone Deacetylase Inhibitor Identified by High-Throughput Transcriptional Screening of a Compound Library," Cancer Research, June 15, 2000, Vol. 60, pp. 3137-3142.	
	B39	UMEHARA et al., "Studies on WF-3161, A New Antitumor Antibiotic," The Journal of Antibiotics, May 1983, pp. 478-483.	
	B40	WATERHOUSE, "CA 19-9 levels in patients with advanced pancreatic cancer (APC) treated in a randomized, phase II trial with the histone deacetylase inhibitor CI-994 + gemcitabine (CI-994+G) versus placebo + gemcitabine (P+G)," American Society of Clinical Oncology (ASCO), 2002 ASCO Annual Meeting, Abstract 589.	
	B41	WILLIAMS, L., "Histone deacetylase inhibitors and other novel agents," American Association for Cancer Research, 93 rd Annual Meeting (Part II), April 6-10, 2002.	
	B42	YOSHIDA et al., "Potent and Specific Inhibition of Mammalian Histone Deacetylase Both <i>in Vivo</i> and <i>in Vitro</i> by Trichostatin A," The Journal of Biological Chemistry, October 5, 1990, Vol. 265, No. 28, pp. 17174-17179.	

Examiner Signature	Date Considered
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